

K970240

MAR 11 1997

Focused Viewer, Inc.
Radiographic Film Illuminator
510(k) Notification

510(k) SUMMARY

1. Name of submitter, address, phone, fax, contact person and date of summary preparation.

Focused Viewer, Inc.
2420 Pasadena Blvd.
Wauwatosa, Wisconsin 53226

The contact person is:

William Brauer, M.D.
Owner

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Summary was prepared on January 14, 1997.

2. Name of device

Trade/Proprietary Name: Diffuser Panel

Common/Usual Names: Translucent front of a Radiographic Film Illuminator

Classification Name: Radiographic Film Illuminator (21 CFR 892.1890)

3. Legally Marketed Equivalent Device Name

We are claiming substantial equivalence to the panel marketed by Diversified Diagnostic Products. Refer to K875233.

510(k) SUMMARY CONTINUED

4. Description of the device


The Diffuser Panel consists of layers of light diffusing and brightness enhancer films, plus a clear polycarbonate panel that is coated with a scratch guard to protect the surface of the brightness enhancer from scratching.

5. Intended use of the device

The Diffuser Panel is designed to diffuse the light from the light source in Radiographic Film Illuminators.

6. Comparison of technological characteristics with predicate device

The function of glass or plastic translucent panels is to diffuse light, and distribute bright light evenly over the x-ray film. The Focused Viewer Diffuser Panel is composed of plastic and is designed to diffuse light and distribute light evenly over the x-ray film in a manner equivalent to marketed devices and to provide at least equivalent brightness.



William Brauer, M.D.
Owner
Focused Viewer, Inc.

JAN 21, 1997

Date